No. 2010-1406

United States Court of Appeals
For the Federal Circuit

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE AMERICAN COLLEGE OF MEDICAL GENETICS, THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, THE COLLEGE OF AMERICAN PATHOLOGISTS, HAIG KAZAZIAN, MD, ARUPA GANGULY, PHD, WENDY CHUNG, MD, PHD, HARRY OSTRER, MD, DAVID LEDBETTER, PHD, STEPHEN WARREN, PHD, ELLEN MATLOFF, M.S., ELSA REICH, M.S., BREAST CANCER ACTION, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD, PATRICE FORTUNE, VICKY THOMASON, and KATHLEEN RAKER,

Plaintiffs-Appellees,

—v.—

UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendant,

—and—

MYRIAD GENETICS, INC.,

Defendant-Appellant,

—and—

LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG, in their official capacity as Directors of The University of Utah Research Foundation,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK, IN CASE NO. 09-CV-4515, SENIOR JUDGE ROBERT W. SWEET

BRIEF FOR AARP AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLEES AND ARGUING FOR AFFIRMANCE

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Association for Molecular Pathology v. United States Patent and Trademark Office, 2010-1406

CERTIFICATE OF INTEREST

Pursuant to Federal Rule of Appellate Procedure 26.1 and Federal Circuit Rule 47.4, counsel for the *Amicus Curiae* AARP certifies the following:

1. The full name of every party or amicus represented by me is: AARP

2. The name of the real party in interest represented by me is: None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are: None.

4. The amicus party did not appear in the trial court. The names of all law firms and the partners or associates who will be appearing before this Court on behalf of the amicus party are:

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

AARP submits this brief as an *amicus curiae* pursuant to Fed. R. App. P. 29(a) and Rule 29(c) of this Court. Both the Plaintiffs-Appellees and the Defendants-Appellants have consented to the filing of this brief.

INTEREST OF *AMICUS CURIAE*

AARP is a nonpartisan, nonprofit organization dedicated to addressing the needs and interests of people age fifty and older. AARP seeks through education, advocacy and service to enhance the quality of life for all by promoting independence, dignity, and purpose. In its efforts to promote independence, AARP works to foster the health and economic security of individuals as they age by attempting to ensure the availability of quality and economical health coverage. AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality.

Access to affordable health care is particularly important to the older population who have higher rates of chronic and serious health conditions. Genetic tests are capable of diagnosing a variety of diseases, assessing the risk of future disease, and enabling treatment to be tailored to individual genetic variations. In 2008, the AARP Public Policy Institute sponsored a roundtable with the National Human Genome Research Institute and the National Institutes of Health entitled *Genomics and Older Adults: Policy, Practice and Promise of 21st Century Medicine* which was held at AARP. AARP has also published a consumer

fact sheet on the Genetic Information Nondiscrimination Act of 2008 (Pub. L. No. 110-233) ("GINA").[1] Patents such as those present in this case prohibit diagnosis and treatment based on second medical opinions and discourage full medical testing. A patent will also significantly elevate the cost of genetic testing. Currently many women decide whether or not to have breasts or ovaries removed based on tests that cannot be independently repeated. In light of the significance of the issue presented in this case, AARP respectfully submits this *amicus curiae* brief urging the Court to find that the patents are invalid.

ARGUMENT

I. HUMAN GENES & DNA MOLECULES ARE NOT PATENT ELIGIBLE UNDER 35 USC §101.

DNA molecules and human genes are natural phenomena that when discovered are not the kind of "discovery" that Section 101 was designed to protect. It has long been clear that the manifestations of the laws and products of nature are not patent eligible. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). *See also Diamond v. Chakrabarty,* 447 U.S. 303, 309 (1980) ("The laws of nature, physical phenomena, and abstract ideas have been held not

[1] N. Lee Rucker, AARP Public Policy Institute, *The GINA Law: Consumer Protection in a New Era of Genetic Testing* (2009), http://assets.aarp.org/rgcenter/health/fs156_gina.pdf.

patentable."); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). "Mere recognition" of an already existing phenomenon is not patentable. *Parker v. Flook*, 437 U.S. 584, 593 n. 15 (1978) ("Patentable subject matter must be new (novel); not merely heretofore unknown."). Further, insignificant physical steps cannot transform unpatentable natural phenomena into a patentable invention. In *Wood-Paper Patent*, 90 U.S. 566 (1874), the Court found that merely removing pulp from straw, wood, or other natural sources did not make it a patentable new composition of matter: "A process to obtain it [an extract] from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture." *Id*. at 593-94. Similarly, isolating a gene from the human body does not then make the gene itself, patentable. Thus, human genes and DNA molecules, regardless of whether they are isolated or not, are natural phenomena and therefore are not patent eligible under 35 U.S.C. §101.

II. PUBLIC HEALTH CONSIDERATIONS DEMAND THAT THE PATENTS IN QUESTION BE DENIED.

In its Opening Brief, *Myriad* notes the "incalculable societal benefits" genetic testing offers and suggests that "future developments will slow or cease" without patent protection. *Myriad* Op. Br. 3-4, citing A3488; A456; A5700-02; A5811-75. *Myriad,* however, fails to discuss potential patient harm if the patents are upheld, even though this Court has looked at such harm if the patents are

upheld. *Cf. Datascope Corp. v. Kontron, Inc.*, 786 F.2d 398 (Fed. Cir. 1986) (Court considered potential patient harm in denying injunctive relief for patent infringement). In this case the public interest demands that the patents in question be denied since many individuals will be harmed if the patent is upheld because genetic testing will be denied to them either due to cost or unavailability of a second opinion.

A. Gene Patents Impede The Ability Of Patients To Obtain A Second Opinion From Other Medical Professionals

Information about human genetic data is accumulating at an ever-increasing pace. Charles N. Rotimi & Lynn B. Jorde, *Ancestry and Disease in the Age of Genomic Medicine*, 363 New Eng. J. Med. 1551 (2010). "Unquestionably, genomics provides novel insights into the causes of and susceptibility to disease and adverse reactions to drugs." *Id.* at 1556. Alzheimer disease, colon and other cancers, in addition to breast cancer are a few of the many diseases subject to genetic testing.

Information gained from genetic tests can have a profound impact on medical decision making. Kathy L. Hudson et al., *Oversight of US Genetic Testing Laboratories*, 24 Nature Biotechnology 1083, 1089 (2006). Test results can lead to important, life-changing decisions, such as whether to undergo prophylactic mastectomy or take a particular drug or dosage of a drug. *Id.* at 1083. Incorrect

test results and laboratory errors can lead to "misdiagnosis, inappropriate and/or delayed treatment, anxiety and in rare cases, even death." *Id.* at 1089. In the relative few instances where BRAC testing was done by other laboratories, occasional different interpretations of genetic sequences and different results were obtained. *See* Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 J. Am. Med. Ass'n 1379 (2006).

Beginning in 2002 and over the next three years, a study was conducted of 300 individuals who had negative test results from Myriad's BRAC analysis but came from families in the United States, each of which included four or more members with breast or ovarian cancer. *Id*. Myriad's BRAC analysis at that time tested for only five specific mutations in the BRCA1 and BRCA2 genes. *See id.* at 1380. Using multiple methods of genetic testing, unlike BRAC analysis, the study found that 35 of the 300, or in other words 12% of the individuals, carried previously undetected BRCA1 or BRCA2 genetic mutations. *See id.* at 1379. Walsh went on to conclude:

> [G]enetic testing, as currently carried out in the United States, does not provide all available information to women at risk . . . [since] 12% of those from high risk families with breast/ovarian cancer and with negative . . . commercial genetic test results for BRCA1 and BRCA2 nonetheless carry cancer-predisposing genomic deletions or duplications in one of these genes.

Id. at 1386. Because an individual with a high risk of breast or ovarian cancer may consider having an invasive and expensive surgical procedure such as a mastectomy, it is extremely important that those who undergo BRCA genetic testing receive accurate and thorough testing and results. *See id.* Walsh also notes that "participation in research studies is not an adequate substitute for providing the most effective and thorough clinical genetic testing." *Id.* While Myriad claims these discrepancies are rare and their tests are now improved, clearly individuals seeking any type of genetic testing should have the option of securing a second opinion which can have life altering results.

Other geneticists have reached different conclusions from Myriad indicating the importance of allowing patients access to second opinions regarding their genetic sequences. In 2001, Dr. Sophia Gad, Dr. Dominique Stoppa-Lyonnet, and a host of other French geneticists identified a large mutation in one woman's BRCA1 gene which was undiscovered by Myriad. *See* Sophia Gad et al., *Identification of a Large Rearrangement of the BRCA1 Gene Using Colour Bar Code on Combed DNA in an American Breast/Ovarian Cancer Family Previously Studied by Direct Sequencing*, 38 J. Med. Genetics 388 (2001). *See also* Declan Butler & Sally Goodman, *French Researchers Take a Stand Against Cancer Gene Patent*, 413 Nature 95 (2001). The woman who participated in this study was diagnosed with breast cancer at age 30 and ovarian cancer at age 49. *See* Gad et

al., *supra*. She also had a sister with ovarian cancer (diagnosed age 35), a sister with breast cancer (diagnosed age 35), and a grandmother with breast cancer (diagnosed age 41). *See id.* She sought testing in an effort to help her daughter identify her specific genetic status with respect to her predisposition to breast and ovarian cancer. *See id.*

The ability to send a sample to a second laboratory is important not only for the patient but also for a laboratory that may receive confusing or unexpected results. *See, e.g.*, Karen P. Mann, *Gene Patents, Perspectives from the Clinical Laboratory*, 14 J. Molecular Diagnosis & Therapy 137, 139 (2010). Confirmatory testing by another laboratory is the "laboratory equivalent to the time-honored practice of obtaining a second opinion from a clinician." U.S. Dept. of Health & Hum. Serv., Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests: Report of the Secretary's Advisory Committee on Genetics, Health, and Society 44 (2010), *available at* http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_patents_report_2010.pdf. ("Access to confirmatory testing is completely impeded when a patent-enabled sole provider exists. That is, patients who desire a confirmatory test from a second laboratory are unable to obtain this second-opinion test in those cases where the patents right holder has cleared the market of other laboratories offering the test.").

B. It Is Critical That Patients Have The Option Of A Second Opinion Given The Limited Governmental Oversight Over Genetic Tests.

The U.S. Dept. of Health and Human Services' Advisory Committee on Genetics, Health & Society, notes that "significant concerns about the quality of a genetic test arise when it is provided by a patent-protected sole provider." *Id.* at 4. The report identified that the "most robust" method for assuring quality in laboratory testing is through the "comparison of results obtained on samples shared between different labs." *Id.* Moreover, the Advisory Committee notes that:

> The presence of multiple laboratories offering competing genetic testing for the same condition can also lead to improvements in the overall quality of testing through innovation in developing novel and more thorough techniques of testing. Neither sample sharing nor competition is possible when an exclusive-rights holder prevents others from providing testing. *Id.*

Most commercially available genetic tests do not encounter the level of government oversight that accompanies the introduction of pharmaceuticals in the marketplace. Eileen M. Kane, *Patent-Mediated Standards in Genetic Testing*, 2008 Utah L. Rev 835, 842 (2008). As a result, a restrictive gene patenting scenario can converge with the lax regulatory climate so that a genetic test may not receive optimal peer assessment. *Id.* Most tests are developed in-house by clinical laboratories and are not subject to government review before they are made clinically available. Hudson, *supra,* at 1083.

When tests are offered by multiple laboratories, quality typically is assessed by the use of international standards as well as by comparison with peers. Mann, *supra* at 139. Obviously, this cannot be done where only a single laboratory conducts testing. With the best proficiency testing, a laboratory will be sent well characterized samples from an external organization or agency to test. Laboratories get information as to what methodology and technology other laboratories are using and how the performance of those laboratories compares. "In the absence of this type of proficiency testing, the ability of the lab to know how well they are doing is impaired." *Id.* Without multiple provider laboratories and this type of proficiency testing, there is simply no way of knowing how proficient a given laboratory is. *Id.*

III. GENE PATENTS LIMIT THE ACCESSIBILITY OF COMPETITIVELY PRICED GENETIC TESTING SO THAT MANY PATIENTS CANNOT AFFORD TESTING.

While advances in genetics and genomics are driving the development of new genetic tests and services, "problems with coverage and reimbursement are limiting their accessibility and integration into the health care system." U.S. Dep't of Health & Hum. Serv., Coverage and Reimbursement of Genetic Tests and Services: Report of the Secretary's Advisory Committee on Genetics, Health, and Society, 9 (2006), *available at* http://www4.od.nih.gov/oba/sacghs/reports/CR_report.pdf (hereafter Coverage and Reimbursement).

Human gene patents can affect patient access through the assignment of exclusive licenses to perform genetic tests. "Exclusive licensing increases cost, as there is a lack of competition." Mann, *supra*, at 139. In addition, there is an increased processing cost for sending out samples and sole provider laboratories may not accept a patient's insurance. *Id.*

In general, gene patents limit the accessibility of competitively priced genetic testing services because of "monopolistic licensing that limits a given genetic test to a single laboratory, royalty-based licensing agreements with exorbitant up-front fees and per-test fees, and licensing agreements that seek proportions of reimbursement from testing services." American College of Medical Genetics, *Position Statement on Gene Patents and Accessibility of Gene Testing* (1999) http://www.acmg.net/StaticContent/StaticPages/Gene_Patents.pdf. "By their nature, patents create an environment of exclusion, and consequently, cripple competition" (*Schering-Plough Corp. v. F.T.C.,* 402 F.3d 1056, 1065-66 (11th Cir. 2005), *cert. den'd,* 548 U.S. 919 (2006)) resulting in elevated prices for the consumer. There are significant numbers of Americans (50.7 million) who are still uninsured. [2] The cost of health care frequently determines whether or not people receive health care. "The failure to obtain health care in a timely fashion is

[2] U.S. Census Bureau, Income, Poverty, and Health Insurance Coverage in the United States: 2009, 22 (2010), *available at* http://www.census.gov/prod/2010 pubs/p60-238.pdf.

associated with negative outcomes, including more costly care, delays in diagnosis or treatment and poorer health outcomes, and premature death." Stefanie Mollborn, Irena Stepanikova, & Karen S. Cook, Delayed Care and Unmet Needs among Health Care System Users: When Does Fiduciary Trust in a Physician Matter?, 40 Health Services Research 1898, 1899 (2005).

A. The Cost of Myriad's BRCA Genetic Testing and Limited Medicare Coverage

Myriad's BRCA genetic testing is expensive, with the most comprehensive tests costing in excess of $4,000, for full sequencing plus rearrangement testing. *See* Myriad Genetic Laboratories, Advanced Beneficiary Notice of Non-Coverage, http://www.myriad.com/lib/abn/Myriad-ABN.pdf (last visited Nov.16, 2010); *Myriad Raises Price of BRCA Testing, Again,* Yale Cancer Genetic Counseling, April 19, 2010, http://yalecancergeneticcounseling.blogspot.com/2010/04/myriad-raises-price-of-brca-testing.html. Medicare is the largest provider of health insurance in the United States[3] and its current coverage policy of genetic testing is limited.[4] Most Medicare beneficiaries live on modest incomes and simply cannot

[3] *See* Medicare.gov, Medicare Benefits, http://www.medicare.gov/navigation/medicare-basics/medicare-benefits/medicare-benefits-overview.aspx (last visited Nov. 30, 2010). Medicare is a Health Insurance Program for people age 65 or older, some disabled people under age 65, and people of all ages with End-Stage Renal Disease.

[4] *Id.* at 30.

afford to pay the elevated costs of patented genetic tests. In 2006, the annual median income among Medicare beneficiaries was $22,800. Nearly half of all beneficiaries (44 percent) have annual family incomes of $20,000 or less. Kaiser Family Found., Medicare Chartbook 15 (4th ed. 2010), *available at http://facts.kff.org/chartbook.aspx?cb=58.* Medicare coverage decisions are made at both the national and local levels. U.S. Dep't of Health & Human Servs., Coverage and Reimbursement, *supra,* at 28.

The U.S. Department of Human and Health Services notes that:

> Most local Medicare administrative contractors do not cover predictive BRCA1/2 testing because they consider it to be a screening test, which [Centers for Medicare and Medicaid Services] has interpreted not to be a statutory benefit. However, a few local Medicare administrative contractors have decided to allow coverage of BRCA testing performed in the absence of signs, symptoms, or a personal history of the disease. The result is that Medicare coverage of the BRCA1/2 genetic test varies depending on where in the United States the beneficiary lives.

Id. at 28. "Different local coverage policies can lead to inconsistencies in coverage from one region to another." *Id*. In some states Medicare will cover the cost of the test if the beneficiary has "a personal history of cancer, injury, or signs/symptoms thereof (i.e. clinically affected)" in addition to one or more of the following: (1) the beneficiary was diagnosed at or before age 45, (2) the beneficiary was diagnosed at or before age 50 or two breast primaries, with one or more close blood relative(s) with epithelial ovarian/fallopian tube/primary peritoneal cancer,

(3) two breast primaries when first breast cancer diagnosis occurred prior to age 50, (4) diagnosed at any age, with two or more close blood relatives with breast and/or epithelial ovarian/fallopian tube/primary peritoneal cancer at any age, (5) Close male blood relative with breast cancer, (5) personal history of epithelial ovarian/fallopian tube/primary peritoneal cancer, (6) if of ethnicity with higher mutation frequency (e.g. Ashkenazi Jewish, Icelandic), no additional family history required, or (7) a close relative with a known BRCA1 or BRCA2 gene mutation.[5]

However, "[p]redictive or pre-symptomatic genetic tests and services in the absence of a past or present illness in the beneficiary, are not covered under national Medicare rules;" for instance, "Medicare does not cover genetic tests based on family history alone." *See* Ctr. Medicare & Medicaid Serv., LCD for Genetic Testing (L24308) (updated Nov. 21, 2010); Ctr. Medicaid & Medicare Serv., Medicare Claims Processing Manuel, Ch.16, Rule 120.1 (2009)("Tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening as described.").

[5] *See* Ctr. Medicare & Medicaid Serv., LCD for Genetic Testing (L23664) (updated Nov. 21, 2010); Ctr. Medicare & Medicaid Serv., LCD for Genetic Testing (L24308) (updated Nov. 21, 2010).

Medicare generally precludes coverage of genetic testing to those people who have not yet been diagnosed with cancer ("testing of unaffected family members or other individuals is considered by Medicare to be screening and is not payable under the Medicare program."). *See* Ctr. Medicare & Medicaid Serv., LCD for Genetic Testing (L24308) (updated Nov. 21, 2010). Requiring that Medicare recipients wait until they actually have contracted cancer reduces one of the most significant benefits of the testing to those BRAC carriers who have not yet contracted cancer but may do so in the future. The most obvious benefit of genetic testing for the BRCA genes is that women with positive test results become aware of their high cancer risk, and, as a result, may follow a suitable preventative strategy to reduce their risk of ever contracting the disease. *See* Marzia Palma et al., *BRCA1 and BRCA2: The Genetic Testing and The Current Management Options For Mutation Carriers*, 57 Critical Rev. in Oncology/Hematology 1, 16 (2006). For carriers of BRCA1 and BRCA2 mutations, the risk of developing breast cancer has been reported to be as high as 87%. *See* Michael J. Hall et al., *BRCA1 and BRCA2 Mutations in Women of Different Ethnicities Undergoing Testing for Hereditary Breast-Ovarian Cancer*, 115 Cancer 2222, 2223 (2009). Unfortunately, most Medicare recipients, living on modest incomes, cannot afford the elevated cost of patented genetic testing.

B. Limited Medicaid Coverage of Genetic Tests and Services

Medicaid covers 45% of all poor Americans. Kaiser Family Found., MEDICAID - A Primer, Key Information on Our Nation's Health Coverage Program for Low-Income People 7 (2010), *available at* http://www.kff.org/medicaid/upload/7334-04.pdf. "Overall, Medicaid beneficiaries are much poorer and in markedly worse health than low-income people with private insurance." *Id.* Medicaid is administered by the states but funded jointly by the state and federal governments.[6] The Federal government mandates that certain benefits be provided to Medicaid recipients, and the States have discretion to cover additional benefits. With the exception of newborn screening, genetic tests and services are optional Medicaid benefits. U.S. Dep't of Health & Human Servs., Coverage and Reimbursement, *supra*, at 5. A number of State Medicaid programs cover BRAC analysis for qualifying individuals, but state requirements vary. Facing Our Risk of Cancer Empowered (FORCE), Medicaid Coverage of Genetic Testing, http://www.facingourrisk.org/info_research/finding-health-care/financial-help/index.php (last visited Dec 6, 2010).

While Myriad does have a special financial assistance program, patients who are recipients of Medicaid or Medicare are not eligible to apply. Myriad, Payment

[6] Kaiser Family Found., MEDICAID - A Primer, *supra,* at 5.

Options and Health Insurance Reimbursement, http://www.myriadtests.com/index.php?page_id=51&usetemplate=pathome&usetype=1 (last visited Dec 6, 2010).

Given the limited coverage of genetic testing for Medicare and Medicaid patients many patients must pay for genetic testing out of their own pockets. Rejecting the patents in this case and allowing more laboratories to do the tests will result in lower prices for the tests and greater patient access.

CONCLUSION

For all of the above-referenced reasons, the judgment of the district court should be affirmed.

Dated: December 8, 2010

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CERTIFICATE OF COMPLIANCE
WITH FED. R. APP. P. 29(d) AND 32(a)(7)(B)

1. This *amicus curiae* brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(d) because it contains 3,432 words.

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Office Word 2007 in Times New Roman14 point font.

Dated: December 8, 2010

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CERTIFICATE OF SERVICE

I hereby certify that on December 8, 2010, I served two paper copies of the foregoing amicus brief in Support of Plaintiffs-Apellees and Arguing for Affirmance via First Class Mail, postage prepaid, on all parties herein to the following address:

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